K091179

JUL 16 2009

April 22, 2009

Monaco RTP System – VMAT Option
Premarket Notification (510(k))
Summary of Safety and Effectiveness

INTRODUCTION

This document summarizes the safety and effectiveness information contained within the Monaco VMAT Premarket Notification (510(k)). The Summary of Safety and Effectiveness contains no confidential or trade secret information and is intended for full public disclosure and distribution.

PREMARKET NOTIFICATION INFORMATION

1. Product Information:
   - a. Product Trade Name — Monaco RTP System
   - b. Release Version Number — VMAT functionality added in release 2.0.0
2. Classification Information:
   - a. Classification Name system — Medical charged-particle radiation therapy
   - b. Common/Usual Name — Radiation Treatment Planning System
   - c. Product Classification — Class II
   - d. Product Code — MUJ
   - e. Reference — 21 CFR 892.5050
   - f. Review Panel — Radiology
3. Establishment Information:
   - a. Submitter — Computerized Medical Systems, Inc.
   - b. Submitter Address — 13723 Riverport Dr. , Suite 100
Maryland Heights, MO 63043
   - c. Establishment Number — 1937649
   - d. Contact — Kathryn Stinson, RA Associate
   - e. Contact Phone — 314-993-0003
   - f. Contact Fax — 314-993-0075

PREDICATE DEVICE INFORMATION

The Monaco RTP System is substantially equivalent to the following device(s) that the Food and Drug Administration (FDA) has cleared for distribution and are currently being actively marketed in the United States. Monaco is substantially equivalent to these product(s) in intended use and safety and effectiveness.

1. Monaco RTP System
   Computerized Medical Systems, Inc.
   K071938

2. ERGO++
   3D Line Medical Systems
   K080601

3. Eclipse Treatment Planning System
   Varian Medical Systems
   K073020

MONACO INTENDED USE

The Monaco system is used to create treatment plans for any cancer patient for whom external beam intensity modulated radiation therapy (IMRT) has been prescribed. The system will calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.

The Monaco product line is intended for use in radiation treatment planning using generally accepted methods for contouring, image manipulation, simulation, image fusion, plan optimization and QA and plan review.

DESCRIPTION OF THE PRODUCT

Monaco uses local biological measures for optimization to create intensity modulated radiation therapy (IMRT) plans using Multileaf Collimators. With the addition of VMAT planning capability, Monaco also allows users to create treatment plans in which the devices that aim and shape the beam are in motion while the beam is on.

LEVEL OF CONCERN

Item 4b of Table 1 in the FDA Guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices asks, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems...." Monaco does not directly control the linear accelerator that delivers the radiation. Once completed, plans are

reviewed and approved by qualified clinicians and may be subject to quality assurance practices before treatment actually takes place. There is no automatic link between the Monaco software and the linear accelerator. However, should a flaw in the treatment plan escape the notice of the qualified professionals using the Monaco system, serious injury or death could result. Therefore, we believe Monaco to be of major level of concern.

SUMMARY OF CLINICAL TESTING

Clinical trials were not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Clinically oriented validation test cases were written and executed in-house by Customer Support personnel in a simulated clinical environment. Algorithm testing was also performed by qualified Medical Physicists using measured data from clinical facilities. Test reports are included in section 20 of this submission.

Monaco with the VMAT option successfully passed both testing efforts and was deemed fit for clinical use.

SUMMARY OF NON-CLINICAL TESTING

Verification tests were written and executed to ensure that the system is working as designed. Pass/fail requirements and results of this testing can be found in the Monaco Verification Test Report, which is included in section 18 of this submission.

Monaco with the VMAT option successfully passed verification testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2009

Ms. Kathryn Stinson
Regulatory Affairs Associate
Computerized Medical Systems, Inc.
13723 Riverport Dr., Suite 100
MARYLAND HEIGHTS MO 63043

Re: K091179
Trade/Device Name: Monaco RTP System – VMAT Option
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: April 22, 2009
Received: April 23, 2009

Dear Ms. Stinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091179

Statement of Indication for Use
Monaco RTP System - VMAT Option 510(k)

The Monaco system is used to create treatment plans for any cancer patient for whom external beam intensity modulated radiation therapy (IMRT) has been prescribed. The system will calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.

The Monaco product line is intended for use in radiation treatment planning using generally accepted methods for contouring, image manipulation, simulation, image fusion, plan optimization and QA and plan review.

Concurrence of the Center for Devices and Radiological Health,
Office of Device Evaluation (ODE)

Prescription Use _X_ OR Over the Counter Use _____
per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091179